

Dingell, Stupak to Investigate Ranbaxy Drug Approvals

Washington, D.C. – Reps. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Bart Stupak (D-MI), Chairman of the Subcommittee on Oversight and Investigations, today launched an investigation into whether the Food and Drug Administration (FDA) knowingly allowed drugs suspected of being fraudulently approved and manufactured in gross violation of Good Manufacturing Practices (GMP) to continue being sold by Ranbaxy, Inc., in the United States.

For Immediate Release: July 22, 2008

Contact: Jodi Seth or Brin Frazier 202-225-5735

Dingell, Stupak to Investigate Ranbaxy Drug Approvals
Question Whether FDA Knowingly Allowed Potentially Unsafe & Ineffective Drugs Into U.S. Market

Washington, D.C.
– Reps. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Bart Stupak (D-MI), Chairman of the Subcommittee on Oversight and Investigations, today launched an investigation into whether the Food and Drug Administration (FDA) knowingly allowed drugs suspected of being fraudulently approved and manufactured in gross violation of Good Manufacturing Practices (GMP) to continue being sold by Ranbaxy, Inc., in the United States.

The investigation was prompted by information contained in a Motion to Enforce Subpoenas and Points and Authorities filed on July 3, 2008, with the U.S. District Court for the District of Maryland.

The Motion, filed by the U.S. Department of Justice and U.S. Attorney's Office on behalf of FDA, states, "Allegations from reliable sources and supporting documents indicate a pattern of systematic fraudulent conduct, including submissions by Ranbaxy to the FDA that contain false and fabricated information about stability and bioequivalence, failure to timely report the distribution of drugs that were out of specification ("OSS"), and attempts to conceal violations of current Good Manufacturing Practices ("cGMPs") regulations from FDA. Specific allegations under investigation include fabricating bioequivalence and stability data to support Abbreviated New Drug Applications ("ANDAs") filed with FDA for generic drugs . . ."

Since January 2007, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have been conducting inquiries into the ability and commitment of the Food and Drug Administration to protect Americans from unsafe food and drugs.

In a letter sent today to FDA Commissioner Andrew C. von Eschenbach, Dingell and Stupak requested information for each drug that Ranbaxy has approval to market in the United States.

[Read the Letter »](#)

Prepared by the Committee on Energy and Commerce

2125 Rayburn House Office Building, Washington, DC 20515